



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
032002

The AOAC Research Institute hereby certifies the method known as:

iQ-Check *Vibrio* Real-Time PCR

Corporate Location
Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, CA 94547 USA

Manufacturing Location
Bio-Rad Laboratories
925 Alfred Nobel Drive
Hercules, CA 94547 USA

This method has been evaluated in the AOAC Research Institute *Performance Tested Methods*SM Program and found to perform as stated in the applicability of the method. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*SM certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

A handwritten signature in black ink that reads "Scott Coates".

Scott Coates, Senior Director
Signature for AOAC Research Institute

Issue Date	October 28, 2023
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METHOD NAME iQ-Check <i>Vibrio</i> Real-Time PCR	CATALOG NUMBER 12006574
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INDEPENDENT LABORATORY Q Laboratories 1930 Radcliff Drive Cincinnati, OH 45204 USA
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APPLICABILITY OF METHOD Analyte: <i>Vibrio</i> species (<i>cholera</i> , <i>parahaemolyticus</i> , <i>vulnificus</i>). Matrixes – cooked shrimp (125 g, 25g), raw mussels (25 g), raw oysters (25 g), raw shrimp (25 g), and raw tuna (25 g) Performance claims – The study data detected no statistical difference between the iQ-Check <i>Vibrio</i> method and the reference methods.	REFERENCE METHOD FDA/BAM Chapter 9: <i>Vibrio</i> . May 2004. (2)
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ORIGINAL CERTIFICATION DATE March 24, 2020	CERTIFICATION RENEWAL RECORD Renewed annually through December 2024.
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METHOD MODIFICATION RECORD	SUMMARY OF MODIFICATION
<ol style="list-style-type: none"> 1. January 2021 Level 1 2. April 2021 Level 1 3. November 2021 Level 1 4. January 2023 Level 2 5. October 2023 Level 1 	<ol style="list-style-type: none"> 1. Editorial/clerical changes. 2. Software was updated from Version 3 to Version 4 allowing compatibility with Windows 10. 3. Editorial changes and addition of user information in French, German, Spanish, Portuguese, and Italian. 4. Addition of CFX Opus Deepwell, with CFX Manager Software, Industrial Diagnostic Edition version 3.1 using Free DNA Removal Solution and Fast APF protocols. 5. Editorial/clerical changes.

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PRINCIPLE OF THE METHOD (1)

The iQ-Check *Vibrio* real-time multiplex PCR kit methods are based on gene amplification and detection by real-time PCR. Ready-to-use PCR reagents contain oligonucleotides (primers and probes) specific for *V. cholerae* (Vc), *V. parahaemolyticus* (Vp), and *V. vulnificus* (Vv), as well as DNA polymerase and nucleotides. Detection and analysis of *Vibrio* species is accomplished with the Bio-Rad CFX96 Touch Deep Well System with the CFX Manager IDE software. In addition, the iQ-Check Prep, a robotic liquid handling platform that performs DNA extraction and PCR plate set-up, can be used to perform the iQ-Check *Vibrio* real-time multiplex PCR kit methods. This allows for a completely integrated automated solution for food pathogen testing. The iQ-Check Free DNA Removal Solution, provided in a separate kit, can also be used with the iQ-Check *Vibrio* real-time multiplex PCR kit methods to optimize removal of free DNA. The iQ-Check *Vibrio* real-time multiplex PCR kit is provided in a ready-to-use format containing all primers, probes, and reagents (except for template DNA) required for the PCR reaction. In addition, an internal positive control (IPC) is included in the reaction mix to identify possible PCR inhibition.

DISCUSSION OF THE VALIDATION STUDY (1)

The iQ-Check *Vibrio* real-time multiplex PCR kit methods successfully detected *Vibrio* species from cook shrimp, raw mussels, raw shrimp, raw oysters, and raw tuna after incubation with VEB for 7-9 h and APW for 6-8 h and 18 h. Using POD analysis, no statistically significant differences were observed between the number of positive samples detected by the candidate methods and the reference methods for all samples tested. The iQ-Check *Vibrio* real-time multiplex PCR kit as a confirmatory method correctly detected *Vibrio* species from TSA+ 2% NaCl, TCBS, and RAPID' *Vibrio* agars. With the addition of the Free DNA Removal Solution, the test kits allow the user to safely reduce free DNA present in the matrixes.

In the inclusivity and exclusivity evaluations, all inclusivity organisms were correctly identified, and all exclusivity organisms were correctly excluded. The inclusivity data also demonstrated that positive isolated colonies from TSA+ 2% NaCl, TCBS, and RAPID' *Vibrio* agars could be tested on the iQ-Check *Vibrio* kit as part of the overall confirmation protocol for *V. cholerae*, *V. parahaemolyticus*, and *V. vulnificus*.

The results obtained by the POD analysis of the product consistency and stability study demonstrated that there were no statistically significant differences between the 3 lots (near the expiration date, near the middle of the expiration period, and recently manufactured). The results obtained by the POD analysis of the robustness study demonstrated that there were no statistically significant differences between the 9 combinations (incubation time, lysis time and Sample/PCR reagent volume) and the nominal method utilized.

The iQ-Check *Vibrio* real-time multiplex PCR kit methods are quick and simple to perform, providing results in less than four hr post incubation of the enrichment for up to 94 sample replicates. The use of the iQ-Check Prep instrument provides a hands-free application that can reduce possible contamination caused by the analyst performing testing. The iQ-Check Prep instrument is able to perform DNA extraction and PCR preparation and provides added value of traceability to the lab. The CFX Manager IDE software is user friendly with the ability to track lot information and sample identification quickly and with ease. Since results are displayed in real-time, the user is able to quickly and accurately determine if results will be valid before the end of the run. The software also provides the user the option to analyze each individual Cq curves to help aid in problem solving any issues within an individual reaction.

Table 3: Inclusivity Results for iQ-Check *Vibrio* Assay Qualitative Detection (1)

No.	Species	Source and Strain #	Origin	iQ-Check <i>Vibrio</i> VEB Broth			iQ-Check <i>Vibrio</i> APW Broth		
				Vc ^d Result	Vp ^e Result	Vv ^f Result	Vc Result	Vp Result	Vv Result
1	<i>V. cholerae</i>	FRO3 G7 ^a	environmental	+	-	-	+	-	-
2	<i>V. cholerae</i>	FRO3 F7 ^a	environmental	+	-	-	+	-	-
3	<i>V. cholerae</i>	FRO3 E7 ^a	environmental	+	-	-	+	-	-
4	<i>V. cholerae</i>	FRO3 D7 ^a	environmental	+	-	-	+	-	-
5	<i>V. cholerae</i>	FRO3 B7 ^a	environmental	+	-	-	+	-	-
6	<i>V. cholerae</i>	FRO3 A7 ^a	environmental	+	-	-	+	-	-
7	<i>V. cholerae</i>	GCSL H10-18 ^a	environmental	+	-	-	+	-	-
8	<i>V. cholerae</i>	GCSL H10-1 ^a	environmental	+	-	-	+	-	-
9	<i>V. cholerae</i>	FRO3 C5 ^a	environmental	+	-	-	+	-	-
10	<i>V. cholerae</i>	FRO3 B5 ^a	environmental	+	-	-	+	-	-
11	<i>V. cholerae</i>	FRO3 A5 ^a	environmental	+	-	-	+	-	-
12	<i>V. cholerae</i>	FRO3 H4 ^a	environmental	+	-	-	+	-	-
13	<i>V. cholerae</i>	FRO3 G4 ^a	environmental	+	-	-	+	-	-
14	<i>V. cholerae</i>	FRO3 F4 ^a	environmental	+	-	-	+	-	-
15	<i>V. cholerae</i>	FRO3 D4 ^a	environmental	+	-	-	+	-	-
16	<i>V. cholerae</i>	FRO3 C7 ^a	environmental	+	-	-	+	-	-
17	<i>V. cholerae</i>	FRO3 B4 ^a	environmental	+	-	-	+	-	-
18	<i>V. cholerae</i>	FRW3 H3 ^a	environmental	+	-	-	+	-	-
19	<i>V. cholerae</i>	FRW3 B1 ^a	environmental	+	-	-	+	-	-
20	<i>V. cholerae</i>	135-17 ^a	unknown	+	-	-	+	-	-
21	<i>V. cholerae</i>	DAL 315 ^a	unknown	+	-	-	+	-	-
22	<i>V. cholerae</i>	G201 ^a	unknown	+	-	-	+	-	-
23	<i>V. cholerae</i>	SPRC HC5C ^a	unknown	+	-	-	+	-	-
24	<i>V. cholerae</i>	CFSAN 8498 ^a	unknown	+	-	-	+	-	-
25	<i>V. cholerae</i>	SPRC O138 ^a	clinical	+	-	-	+	-	-
26	<i>V. cholerae</i>	G12R ^a	unknown	+	-	-	+	-	-
27	<i>V. cholerae</i>	SPRC HC2B ^a	environmental	+	-	-	+	-	-

28	<i>V. cholerae</i>	D1042 ^a	unknown	+	-	-	+	-	-
29	<i>V. cholerae</i>	ATCC 14103 ^c	unknown	+	-	-	+	-	-
30	<i>V. cholerae</i>	17-17 ^a	environmental	+	-	-	+	-	-
31	<i>V. cholerae</i>	25-16 ^a	environmental	+	-	-	+	-	-
32	<i>V. cholerae</i>	C-6707 ^a	clinical	+	-	-	+	-	-
33	<i>V. cholerae</i>	1800-62 ^a	unknown	+	-	-	+	-	-
34	<i>V. cholerae</i>	VRL 1984 ^a	clinical	+	-	-	+	-	-
35	<i>V. cholerae</i>	569B ^a	clinical	+	-	-	+	-	-
36	<i>V. cholerae</i>	CDC 2463-88 ^b	clinical	+	-	-	+	-	-
37	<i>V. cholerae</i>	UCIC 305E ^a	environmental	+	-	-	+	-	-
38	<i>V. cholerae</i>	709-1 ^a	environmental	+	-	-	+	-	-
39	<i>V. cholerae</i>	154 ^a	environmental	+	-	-	+	-	-
40	<i>V. cholerae</i>	C-153 ^a	unknown	+	-	-	+	-	-
41	<i>V. cholerae</i>	UCIC 305C ^a	environmental	+	-	-	+	-	-
42	<i>V. cholerae</i>	O145B ^a	clinical	+	-	-	+	-	-
43	<i>V. cholerae</i>	CDC 3523-03	clinical	+	-	-	+	-	-
44	<i>V. cholerae</i>	CDC 2164-78	clinical	+	-	-	+	-	-
45	<i>V. cholerae</i>	CDC 3525-97	clinical	+	-	-	+	-	-
46	<i>V. cholerae</i>	CDC 3541-98	clinical	+	-	-	+	-	-
47	<i>V. cholerae</i>	SJ 21 ^a	environmental	+	-	-	+	-	-
48	<i>V. cholerae</i>	CDC F851 ^b	clinical	+	-	-	+	-	-
49	<i>V. cholerae</i>	C-6706 ^a	clinical	+	-	-	+	-	-
50	<i>V. cholerae</i>	CDC 3569-03	clinical	+	-	-	+	-	-
51	<i>V. parahaemolyticus</i>	331 17B ^a	environmental	-	+	-	-	+	-
52	<i>V. parahaemolyticus</i>	888 9-1 ^a	oyster	-	+	-	-	+	-
53	<i>V. parahaemolyticus</i>	CDC K5439	clinical	-	+	-	-	+	-
54	<i>V. parahaemolyticus</i>	CDC K5277	clinical	-	+	-	-	+	-
55	<i>V. parahaemolyticus</i>	CDC K5067	clinical	-	+	-	-	+	-
56	<i>V. parahaemolyticus</i>	CDC K4557	clinical	-	+	-	-	+	-
57	<i>V. parahaemolyticus</i>	FDA R149 ^a	oyster	-	+	-	-	+	-
58	<i>V. parahaemolyticus</i>	FDA R130 ^a	oyster	-	+	-	-	+	-
59	<i>V. parahaemolyticus</i>	FDA R75 ^a	oyster	-	+	-	-	+	-
60	<i>V. parahaemolyticus</i>	FDA R2 ^a	oyster	-	+	-	-	+	-
61	<i>V. parahaemolyticus</i>	NY477 ^a	oyster	-	+	-	-	+	-
62	<i>V. parahaemolyticus</i>	SPRC 10293 ^a	clinical	-	+	-	-	+	-

63	<i>V. parahaemolyticus</i>	SAK11 ^a	clinical	-	+	-	-	+	-
64	<i>V. parahaemolyticus</i>	BAC-98-3547 ^a	clinical	-	+	-	-	+	-
65	<i>V. parahaemolyticus</i>	CT02006286 ^a	clinical	-	+	-	-	+	-
66	<i>V. parahaemolyticus</i>	HC-20-01 ^a	environmental	-	+	-	-	+	-
67	<i>V. parahaemolyticus</i>	CT02006628 ^a	clinical	-	+	-	-	+	-
68	<i>V. parahaemolyticus</i>	HC-05-01 ^a	environmental	-	+	-	-	+	-
69	<i>V. parahaemolyticus</i>	BAC-98-3483 ^a	clinical	-	+	-	-	+	-
70	<i>V. parahaemolyticus</i>	DAL 1094 ^a	unknown	-	+	-	-	+	-
71	<i>V. parahaemolyticus</i>	049-2A ^a	oyster	-	+	-	-	+	-
72	<i>V. parahaemolyticus</i>	10329 ^a	clinical	-	+	-	-	+	-
73	<i>V. parahaemolyticus</i>	9401416 ^a	clinical	-	+	-	-	+	-
74	<i>V. parahaemolyticus</i>	48215 ^a	clinical	-	+	-	-	+	-
75	<i>V. parahaemolyticus</i>	954625 ^a	unknown	-	+	-	-	+	-
76	<i>V. parahaemolyticus</i>	9401392 ^a	clinical	-	+	-	-	+	-
77	<i>V. parahaemolyticus</i>	14D1 ^a	environmental	-	+	-	-	+	-
78	<i>V. parahaemolyticus</i>	VP43-1A ^a	unknown	-	+	-	-	+	-
79	<i>V. parahaemolyticus</i>	659 110-1 ^a	environmental	-	+	-	-	+	-
80	<i>V. parahaemolyticus</i>	330 3B ^a	environmental	-	+	-	-	+	-
81	<i>V. parahaemolyticus</i>	330 6 ^a	environmental	-	+	-	-	+	-
82	<i>V. parahaemolyticus</i>	1300 A2-1 ^a	environmental	-	+	-	-	+	-
83	<i>V. parahaemolyticus</i>	337 111 ^a	environmental	-	+	-	-	+	-
84	<i>V. parahaemolyticus</i>	872 247-1 ^a	environmental	-	+	-	-	+	-
85	<i>V. parahaemolyticus</i>	AO-24491 ^a	clinical	-	+	-	-	+	-
86	<i>V. parahaemolyticus</i>	AP-11243 ^a	clinical	-	+	-	-	+	-
87	<i>V. parahaemolyticus</i>	AN-2189 ^a	clinical	-	+	-	-	+	-
88	<i>V. parahaemolyticus</i>	DI-B9 3/16 ^a	environmental	-	+	-	-	+	-
89	<i>V. parahaemolyticus</i>	TX 2103 ^a	clinical	-	+	-	-	+	-
90	<i>V. parahaemolyticus</i>	SPRC 10295 ^a	clinical	-	+	-	-	+	-
91	<i>V. parahaemolyticus</i>	FIHES-98-V1 ^a	clinical	-	+	-	-	+	-
92	<i>V. parahaemolyticus</i>	AQ 4913 ^a	clinical	-	+	-	-	+	-
93	<i>V. parahaemolyticus</i>	DI-E12 5/26 ^a	environmental	-	+	-	-	+	-
94	<i>V. parahaemolyticus</i>	F11-3A ^a	environmental	-	+	-	-	+	-
95	<i>V. parahaemolyticus</i>	48057 ^a	clinical	-	+	-	-	+	-
96	<i>V. parahaemolyticus</i>	R57 ^a	oyster	-	+	-	-	+	-
97	<i>V. parahaemolyticus</i>	R51 ^a	oyster	-	+	-	-	+	-

98	<i>V. parahaemolyticus</i>	R31 ^a	oyster	-	+	-	-	+	-
99	<i>V. parahaemolyticus</i>	R10 ^a	oyster	-	+	-	-	+	-
100	<i>V. parahaemolyticus</i>	R5 ^a	oyster	-	+	-	-	+	-
101	<i>V. vulnificus</i>	AM47548 ^a	clinical	-	-	+	-	-	+
102	<i>V. vulnificus</i>	1007(O) ^a	unknown	-	-	+	-	-	+
103	<i>V. vulnificus</i>	94-8-109 ^a	unknown	-	-	+	-	-	+
104	<i>V. vulnificus</i>	BUF 7211 ^a	clinical	-	-	+	-	-	+
105	<i>V. vulnificus</i>	R844-G9 ^a	environmental	-	-	+	-	-	+
106	<i>V. vulnificus</i>	NSV 5736 (CDC 9349-95) ^a	clinical	-	-	+	-	-	+
107	<i>V. vulnificus</i>	K4767 ^a	clinical	-	-	+	-	-	+
108	<i>V. vulnificus</i>	DAL 79040 (CDC 9070-96) ^a	clinical	-	-	+	-	-	+
109	<i>V. vulnificus</i>	ATL 9824 ^a	clinical	-	-	+	-	-	+
110	<i>V. vulnificus</i>	ATL 9579 ^a	clinical	-	-	+	-	-	+
111	<i>V. vulnificus</i>	99-520 DP-B8 ^a	oyster	-	-	+	-	-	+
112	<i>V. vulnificus</i>	99-584 DP-B12 ^a	oyster	-	-	+	-	-	+
113	<i>V. vulnificus</i>	99-578 DP-B1 ^a	oyster	-	-	+	-	-	+
114	<i>V. vulnificus</i>	99-796 DP-E7 ^a	oyster	-	-	+	-	-	+
115	<i>V. vulnificus</i>	98-641 DP-G8 ^a	oyster	-	-	+	-	-	+
116	<i>V. vulnificus</i>	99-780 DP-E1 ^a	oyster	-	-	+	-	-	+
117	<i>V. vulnificus</i>	2095/00 ^a	environmental	-	-	+	-	-	+
118	<i>V. vulnificus</i>	98-640 DP-E9 ^a	oyster	-	-	+	-	-	+
119	<i>V. vulnificus</i>	99-645 DP-C4 ^a	oyster	-	-	+	-	-	+
120	<i>V. vulnificus</i>	ATCC 33816 ^c	clinical	-	-	+	-	-	+
121	<i>V. vulnificus</i>	1003(O) ^a	unknown	-	-	+	-	-	+
122	<i>V. vulnificus</i>	LOS 7506 ^a	clinical	-	-	+	-	-	+
123	<i>V. vulnificus</i>	ATL 64138(12) ^a	clinical	-	-	+	-	-	+
124	<i>V. vulnificus</i>	NSV 5829 (CDC 9149-95) ^a	clinical	-	-	+	-	-	+
125	<i>V. vulnificus</i>	DAL 8-9131(7) ^a	clinical	-	-	+	-	-	+
126	<i>V. vulnificus</i>	ORL 8073 ^a	clinical	-	-	+	-	-	+
127	<i>V. vulnificus</i>	R499-A8 ^a	oyster	-	-	+	-	-	+
128	<i>V. vulnificus</i>	99-779 DP-D2 ^a	oyster	-	-	+	-	-	+
129	<i>V. vulnificus</i>	99-624 DP-C10 ^a	oyster	-	-	+	-	-	+
130	<i>V. vulnificus</i>	94-9-146 ^a	unknown	-	-	+	-	-	+
131	<i>V. vulnificus</i>	94-8-111 ^a	unknown	-	-	+	-	-	+
132	<i>V. vulnificus</i>	ATL 71491 (CDC 9074-96) ^a	clinical	-	-	+	-	-	+

133	<i>V. vulnificus</i>	LOS 7343 (CDC 9062-96) ^a	clinical	-	-	+	-	-	+
134	<i>V. vulnificus</i>	FLA 9509 (CDC 9003-97) ^a	clinical	-	-	+	-	-	+
135	<i>V. vulnificus</i>	ORL 8324 (CDC 9340-95) ^a	clinical	-	-	+	-	-	+
136	<i>V. vulnificus</i>	ATL 9823 (CDC 9352-94) ^a	clinical	-	-	+	-	-	+
137	<i>V. vulnificus</i>	ATL 7-1503 (CDC 9075-96) ^a	clinical	-	-	+	-	-	+
138	<i>V. vulnificus</i>	DAL 6-5000 (CDC 9345-95) ^a	clinical	-	-	+	-	-	+
139	<i>V. vulnificus</i>	ORL 8074 (CDC 9032-95) ^a	clinical	-	-	+	-	-	+
140	<i>V. vulnificus</i>	ATL 6-1306 (CDC 9031-96) ^a	clinical	-	-	+	-	-	+
141	<i>V. vulnificus</i>	LOS 6966 (CDC 9342-95) ^a	clinical	-	-	+	-	-	+
142	<i>V. vulnificus</i>	FLA 8869 (CDC 9053-96) ^a	clinical	-	-	+	-	-	+
143	<i>V. vulnificus</i>	ATL 71504 (CDC 9076-96) ^a	clinical	-	-	+	-	-	+
144	<i>V. vulnificus</i>	99-622 DP-E4 ^a	oyster	-	-	+	-	-	+
145	<i>V. vulnificus</i>	99-609 DP-A4 ^a	oyster	-	-	+	-	-	+
146	<i>V. vulnificus</i>	99-623 DP-F5 ^a	oyster	-	-	+	-	-	+
147	<i>V. vulnificus</i>	99-742 DP-A9 ^a	oyster	-	-	+	-	-	+
148	<i>V. vulnificus</i>	99-537 DP-G7 ^a	oyster	-	-	+	-	-	+
149	<i>V. vulnificus</i>	98-783 DP-A1 ^a	oyster	-	-	+	-	-	+
150	<i>V. vulnificus</i>	99-743 DP-B6 ^a	oyster	-	-	+	-	-	+

^aUS FDA MESC/Dauphin Island Sea Laboratory, Dauphin Island, AL

^bCenter for Disease Control and Prevention, Atlanta, GA

^cATCC = American Type Culture Collection, Manassas, VA

^dVc = *Vibrio cholera*

^eVp = *Vibrio parahaemolyticus*

^fVv = *Vibrio vulnificus*

Table 4: Exclusivity Results for iQ-Check *Vibrio* Assay Qualitative Detection (1)

No.	Species	Source and Strain #	Origin	iQ-Check <i>Vibrio</i> TSB Broth		
				Vc ^k Result	Vp ^l Result	Vv ^m Result
1	<i>V. aesturianus</i>	CIP 10297 ^a	Oyster	-	-	-
2	<i>V. alginolyticus</i>	ATCC 33787 ^b	Unknown	-	-	-
3	<i>V. alginolyticus</i>	1296-1 ^c	environmental	-	-	-
4	<i>V. alginolyticus</i>	2208-1B ^c	environmental	-	-	-
5	<i>V. anguillarum</i>	CIP 63.36T	Cod	-	-	-
6	<i>V. fluvialis</i>	1959-82 ^c	clinical	-	-	-
7	<i>V. fluvialis</i>	DAL 1825 ^c	clinical	-	-	-
8	<i>V. fluvialis</i>	11961 ^c	Unknown	-	-	-
9	<i>V. fluvialis</i>	DAL 1678 ^c	Unknown	-	-	-
10	<i>V. fluvialis</i>	DAL 197 ^c	Unknown	-	-	-
11	<i>V. fluvialis</i>	DAL 506 ^c	Unknown	-	-	-
12	<i>V. furnissii</i>	1955-83 ^c	clinical	-	-	-
13	<i>V. harveyi</i>	CIP104172	Brown shark	-	-	-
14	<i>V. hollisae</i>	CIP 101886T	Human feces	-	-	-
15	<i>V. mediterranei</i>	CIP103203T	Coastal sediment	-	-	-
16	<i>V. metschnikovii</i>	2477 ^c	Unknown	-	-	-
17	<i>V. metschnikovii</i>	2908-8 ^c	Unknown	-	-	-
18	<i>V. metschnikovii</i>	10917 ^c	Unknown	-	-	-
19	<i>V. mimicus</i>	CIP 101888T	Human	-	-	-
20	<i>V. natrigens</i>	CIP103193T	Salt marsh mud	-	-	-
21	<i>V. tubiashii</i>	CIP102760T	Hard clams	-	-	-
22	<i>Enterobacter sakazakii</i>	ATCC BAA-894	Human	-	-	-
23	<i>Aeromonas hydrophila</i>	LMG2844T ^d	Unknown	-	-	-
24	<i>Staphylococcus xylosum</i>	ATCC 15305	Urine	-	-	-
25	<i>Aeromonas viridans</i>	QL 17041.8 ^e	Raw Milk	-	-	-
26	<i>Alternaria alternata</i>	DSM 1102 ^f	Unknown	-	-	-
27	<i>Aspergillus brasiliensis (ex niger)</i>	DSM 1988 (ATCC 16404)	Unknown	-	-	-
28	<i>Aspergillus restrictus</i>	CECT 20807 ^g	Unknown	-	-	-
29	<i>Bacillus cereus</i>	ATCC 10876	Unknown	-	-	-

30	<i>Klebsiella pneumoniae ssp pneumoniae</i>	ATCC 700603D-5	Unknown	-	-	-
31	<i>Campylobacter coli</i>	ATCC 43489	Unknown	-	-	-
32	<i>Campylobacter jejuni</i>	ATCC 29428	Unknown	-	-	-
33	<i>Campylobacter lari</i>	ATCC 35221	Unknown	-	-	-
34	<i>Klebsiella oxytoca</i>	ATCC 700324	Unknown	-	-	-
35	<i>Candida albicans</i>	ATCC 10231	Unknown	-	-	-
36	<i>Candida tropicalis</i>	ATCC 750	Unknown	-	-	-
37	<i>Citrobacter freundii</i>	ATCC8090	Unknown	-	-	-
38	<i>Clostridium perfringens</i>	CIP103409	Unknown	-	-	-
39	<i>Cronobacter sakazakii</i>	ATCC 29544	Child's throat	-	-	-
40	<i>Debaryomyces hansenii</i>	ATCC 10619	Unknown	-	-	-
41	<i>Enterobacter aerogenes</i>	ATCC13048	Unknown	-	-	-
42	<i>Salmonella</i> Enteritidis	ATCC 13076	Unknown	-	-	-
43	<i>Raoultella terrigena</i>	ATCC 33629	Water	-	-	-
44	<i>Enterobacter cloacae</i>	LMG2783	Unknown	-	-	-
45	<i>Enterobacter amnigenus</i>	ATCC 51818	Milk	-	-	-
46	<i>Enterobacter pyrinus</i>	ATCC 49851	Unknown	-	-	-
47	<i>Escherichia hermannii</i>	ATCC 33650	Human	-	-	-
48	<i>Enterococcus faecium</i>	CECT 8293	Unknown	-	-	-
49	<i>Escherichia coli</i>	ATCC 700728	Unknown	-	-	-
50	<i>Campylobacter upsaliensis</i>	ATCC 49816	Human feces	-	-	-
51	<i>Eurotium rubrum</i>	CECT 20808	Unknown	-	-	-
52	<i>Fusarium graminearum</i>	DSM 1096	Unknown	-	-	-
53	<i>Geotrichum candidum</i>	DSM 10452	Unknown	-	-	-
54	<i>Grimontia hollisae</i>	98A1960 ^a	Unknown	-	-	-
55	<i>Hafnia alvei</i>	CIP57.31T	Unknown	-	-	-
56	<i>Acinetobacter baumannii</i>	ATCC 19606	Urine	-	-	-
57	<i>Pantoea agglomerans</i>	ATCC 27155	Human	-	-	-
58	<i>Kluyveromyces lactis</i>	ATCC 8585	Unknown	-	-	-
59	<i>Enterobacter hormaechei</i>	ATCC 49162	Human	-	-	-
60	<i>Listeria cornellensis</i>	FSL F6-0969 ^h	Water	-	-	-
61	<i>Listeria fleischmannii</i>	FSL S10-1203	Unknown	-	-	-
62	<i>Listeria floridensis</i>	FSL S10-1187	Running Water	-	-	-
63	<i>Listeria grandensis</i>	FSL F6-0971	Water	-	-	-
64	<i>Listeria grayi</i>	ATCC 19120	Animal Feces	-	-	-

65	<i>Listeria innocua</i>	ATCC 33090	Cow Brain	-	-	-
66	<i>Listeria ivanovii</i>	ATCC BAA-139	Washing Water	-	-	-
67	<i>Listeria monocytogenes</i>	CNR L103573 ⁱ	Unknown	-	-	-
68	<i>Listeria riparia</i>	FSL S10-1204	Running Water	-	-	-
69	<i>Listeria rocourtaie</i>	FSL F6-0920	Unknown	-	-	-
70	<i>Listeria seeligeri</i>	FSL S4-035	Unknown	-	-	-
71	<i>Listeria weihenstephanensis</i>	FSL R9-0317	Unknown	-	-	-
72	<i>Listeria welshimeri</i>	ATCC 35897	Unknown	-	-	-
73	<i>Bacillus licheniformis</i>	ATCC 39326	Soil	-	-	-
74	<i>Mucor racemosus</i>	CECT 20821	Unknown	-	-	-
75	<i>Lactobacillus casei</i>	ATCC 393	Dairy	-	-	-
76	<i>Penicillium hirsutum (ex cyclopium)</i>	ATCC 16025	Unknown	-	-	-
77	<i>Photobacterium damsela</i>	BR-D1-100 ^c	environmental	-	-	-
78	<i>Photobacterium damsela</i>	BR-901 ^c	environmental	-	-	-
79	<i>Photobacterium damsela</i>	LSU ^c	environmental	-	-	-
80	<i>Kregervanrija delftensis</i>	ATCC 22305	Unknown	-	-	-
81	<i>Proteus mirabilis</i>	ATCC 29906	Unknown	-	-	-
82	<i>Pseudomonas aeruginosa</i>	TH ^c	Unknown	-	-	-
83	<i>Pseudomonas fluorescens</i>	ATCC 13525	Pre-filter tanks	-	-	-
84	<i>Micrococcus luteus</i>	ATCC 4698	Unknown	-	-	-
85	<i>Rhodotorula mucilaginosa</i>	ATCC 9449	Unknown	-	-	-
86	<i>Saccharomyces bayanus</i>	ATCC 62014	Unknown	-	-	-
87	<i>Saccharomyces cerevisiae</i>	DSM 1333	Unknown	-	-	-
88	<i>Salmonella arizonae</i>	CECT 4395	Unknown	-	-	-
89	<i>Salmonella Berta</i>	CMF 141.2	Unknown	-	-	-
90	<i>Salmonella bongori</i>	CIP 82.33T	Unknown	-	-	-
91	<i>Salmonella diarizonae</i>	CIP 82.31T	Unknown	-	-	-
92	<i>Salmonella Dublin</i>	CIP 106222	Unknown	-	-	-
93	<i>Aeromonas hydrophila/caviae</i>	ATCC 13136	Unknown	-	-	-
94	<i>Salmonella houtenae</i>	CIP82.32T	Unknown	-	-	-
95	<i>Salmonella salamae</i>	CECT 4000	Unknown	-	-	-
96	<i>Serratia liquefacians</i>	25792 ^c	Unknown	-	-	-
97	<i>Serratia marcescens</i>	ATCC 8100	Unknown	-	-	-
98	<i>Shewanella putrefaciens</i>	FT-507 ^c	Unknown	-	-	-
99	<i>Shigella boydii</i>	ATCC 9207	Pork Liver	-	-	-

100	<i>Shigella flexneri</i>	ATCC 12022	Unknown	-	-	-
101	<i>Shigella sonnei</i>	ATCC 25931	Unknown	-	-	-
102	<i>Siccibacter turicensis</i>	CCUG 54945 ^l	Unknown	-	-	-
103	<i>Staphylococcus aureus</i>	ATCC 25923	Unknown	-	-	-
104	<i>Staphylococcus epidermidis</i>	ATCC 14990	Nose	-	-	-
105	<i>Staphylococcus haemolyticus</i>	ATCC 29970	Human Skin	-	-	-
106	<i>Staphylococcus hominis</i>	ATCC 27844	Human Skin	-	-	-
107	<i>Staphylococcus intermedius</i>	61.221 ^c	Unknown	-	-	-
108	<i>Staphylococcus sciuri</i>	QL 17041.9	Raw Milk	-	-	-
109	<i>Staphylococcus warneri</i>	ATCC 29885	Unknown	-	-	-
110	<i>Enterobacter asburiae</i>	ATCC 35956	Human	-	-	-
111	<i>Streptococcus agalactiae</i>	ATCC BAA-22	Unknown	-	-	-
112	<i>Streptococcus pneumoniae</i>	ATCC 6301	Unknown	-	-	-
113	<i>Streptococcus pyogenes</i>	ATCCC 19615	Child's Pharynx	-	-	-
114	<i>Wallemia sebi</i>	CECT 20820	Unknown	-	-	-
115	<i>Yersinia enterocolitica</i>	CIP 80.27T	Unknown	-	-	-
116	<i>Zygosaccharomyces rouxii</i>	DSM 7525	Unknown	-	-	-

^aCIP=Collection Institute Pasteur, Paris, France

^bATCC = American Type Culture Collection, Manassas, VA

^cUS FDA MESC/Dauphin Island Sea Laboratory, Dauphin Island, AL

^dLMG=Belgian Coordinated Collections of Microorganisms, Ghent, Belgium

^eQL = Q Laboratories, Cincinnati, OH

^fDSM=The Leibniz Institute DSMZ, Brunswick, Germany

^gCECT=Spanish Type Culture Collection. Valencia, Spain

^hFSL= Cornell University, Ithaca, NY

ⁱCNR= **Centre National de référence des Legionelles, Lyon, France**

^jCCUG= Culture Collection University of Gothenburg, DSMZ, Braunschweig, Germany

^kVc = *Vibrio cholera*

^lVp = *Vibrio parahaemolyticus*

^mVv = *Vibrio vulnificus*

Table 5: Inclusivity Results for the iQ-Check *Vibrio* Assay from Select Agars (1)

No.	Species	Source and Strain #	Origin	TSA + 2% NaCl Plate			TCBS Plate			RAPID [®] <i>Vibrio</i> Plate		
				Vc ^d Result	Vp ^e Result	Vv ^f Result	Vc Result	Vp Result	Vv Result	Vc Result	Vp Result	Vv Result
1	<i>V. cholerae</i>	FRO3 G7 ^a	environmental	+	-	-	+	-	-	+	-	-
2	<i>V. cholerae</i>	FRO3 F7 ^a	environmental	+	-	-	+	-	-	+	-	-
3	<i>V. cholerae</i>	FRO3 E7 ^a	environmental	+	-	-	+	-	-	+	-	-
4	<i>V. cholerae</i>	FRO3 D7 ^a	environmental	+	-	-	+	-	-	+	-	-
5	<i>V. cholerae</i>	FRO3 B7 ^a	environmental	+	-	-	+	-	-	+	-	-
6	<i>V. cholerae</i>	FRO3 A7 ^a	environmental	+	-	-	+	-	-	+	-	-
7	<i>V. cholerae</i>	GCSL H10-18 ^a	environmental	+	-	-	+	-	-	+	-	-
8	<i>V. cholerae</i>	GCSL H10-1 ^a	environmental	+	-	-	+	-	-	+	-	-
9	<i>V. cholerae</i>	FRO3 C5 ^a	environmental	+	-	-	+	-	-	+	-	-
10	<i>V. cholerae</i>	FRO3 B5 ^a	environmental	+	-	-	+	-	-	+	-	-
11	<i>V. cholerae</i>	FRO3 A5 ^a	environmental	+	-	-	+	-	-	+	-	-
12	<i>V. cholerae</i>	FRO3 H4 ^a	environmental	+	-	-	+	-	-	+	-	-
13	<i>V. cholerae</i>	FRO3 G4 ^a	environmental	+	-	-	+	-	-	+	-	-
14	<i>V. cholerae</i>	FRO3 F4 ^a	environmental	+	-	-	+	-	-	+	-	-
15	<i>V. cholerae</i>	FRO3 D4 ^a	environmental	+	-	-	+	-	-	+	-	-
16	<i>V. cholerae</i>	FRO3 C7 ^a	environmental	+	-	-	+	-	-	+	-	-
17	<i>V. cholerae</i>	FRO3 B4 ^a	environmental	+	-	-	+	-	-	+	-	-
18	<i>V. cholerae</i>	FRW3 H3 ^a	environmental	+	-	-	+	-	-	+	-	-
19	<i>V. cholerae</i>	FRW3 B1 ^a	environmental	+	-	-	+	-	-	+	-	-
20	<i>V. cholerae</i>	135-17 ^a	unknown	+	-	-	+	-	-	+	-	-
21	<i>V. cholerae</i>	DAL 315 ^a	unknown	+	-	-	+	-	-	+	-	-
22	<i>V. cholerae</i>	G201 ^a	unknown	+	-	-	+	-	-	+	-	-
23	<i>V. cholerae</i>	SPRC HC5C ^a	unknown	+	-	-	+	-	-	+	-	-
24	<i>V. cholerae</i>	CFSAN 8498 ^a	unknown	+	-	-	+	-	-	+	-	-
25	<i>V. cholerae</i>	SPRC O138 ^a	clinical	+	-	-	+	-	-	+	-	-
26	<i>V. cholerae</i>	G12R ^a	unknown	+	-	-	+	-	-	+	-	-
27	<i>V. cholerae</i>	SPRC HC2B ^a	environmental	+	-	-	+	-	-	+	-	-
28	<i>V. cholerae</i>	D1042 ^a	unknown	+	-	-	+	-	-	+	-	-
29	<i>V. cholerae</i>	ATCC 14103	unknown	+	-	-	+	-	-	+	-	-
30	<i>V. cholerae</i>	17-17 ^a	environmental	+	-	-	+	-	-	+	-	-

31	<i>V. cholerae</i>	25-16 ^a	environmental	+	-	-	+	-	-	+	-	-
32	<i>V. cholerae</i>	C-6707 ^a	clinical	+	-	-	+	-	-	+	-	-
33	<i>V. cholerae</i>	1800-62 ^a	unknown	+	-	-	+	-	-	+	-	-
34	<i>V. cholerae</i>	VRL 1984 ^a	clinical	+	-	-	+	-	-	+	-	-
35	<i>V. cholerae</i>	569B ^a	clinical	+	-	-	+	-	-	+	-	-
36	<i>V. cholerae</i>	CDC 2463-88	clinical	+	-	-	+	-	-	+	-	-
37	<i>V. cholerae</i>	UCIC 305E	environmental	+	-	-	+	-	-	+	-	-
38	<i>V. cholerae</i>	709-1	environmental	+	-	-	+	-	-	+	-	-
39	<i>V. cholerae</i>	154	environmental	+	-	-	+	-	-	+	-	-
40	<i>V. cholerae</i>	C-153	unknown	+	-	-	+	-	-	+	-	-
41	<i>V. cholerae</i>	UCIC 305C	environmental	+	-	-	+	-	-	+	-	-
42	<i>V. cholerae</i>	O145B	clinical	+	-	-	+	-	-	+	-	-
43	<i>V. cholerae</i>	CDC 3523-03	clinical	+	-	-	+	-	-	+	-	-
44	<i>V. cholerae</i>	CDC 2164-78	clinical	+	-	-	+	-	-	+	-	-
45	<i>V. cholerae</i>	CDC 3525-97	clinical	+	-	-	+	-	-	+	-	-
46	<i>V. cholerae</i>	CDC 3541-98	clinical	+	-	-	+	-	-	+	-	-
47	<i>V. cholerae</i>	SJ 21	environmental	+	-	-	+	-	-	+	-	-
48	<i>V. cholerae</i>	CDC F851	clinical	+	-	-	+	-	-	+	-	-
49	<i>V. cholerae</i>	C-6706	clinical	+	-	-	+	-	-	+	-	-
50	<i>V. cholerae</i>	CDC 3569-03	clinical	+	-	-	+	-	-	+	-	-
51	<i>V. parahaemolyticus</i>	331 17B	environmental	-	+	-	-	+	-	-	+	-
52	<i>V. parahaemolyticus</i>	888 9-1	oyster	-	+	-	-	+	-	-	+	-
53	<i>V. parahaemolyticus</i>	CDC K5439	clinical	-	+	-	-	+	-	-	+	-
54	<i>V. parahaemolyticus</i>	CDC K5277	clinical	-	+	-	-	+	-	-	+	-
55	<i>V. parahaemolyticus</i>	CDC K5067	clinical	-	+	-	-	+	-	-	+	-
56	<i>V. parahaemolyticus</i>	CDC K4557	clinical	-	+	-	-	+	-	-	+	-
57	<i>V. parahaemolyticus</i>	FDA R149	oyster	-	+	-	-	+	-	-	+	-
58	<i>V. parahaemolyticus</i>	FDA R130	oyster	-	+	-	-	+	-	-	+	-
59	<i>V. parahaemolyticus</i>	FDA R75	oyster	-	+	-	-	+	-	-	+	-
60	<i>V. parahaemolyticus</i>	FDA R2	oyster	-	+	-	-	+	-	-	+	-
61	<i>V. parahaemolyticus</i>	NY477	oyster	-	+	-	-	+	-	-	+	-
62	<i>V. parahaemolyticus</i>	SPRC 10293	clinical	-	+	-	-	+	-	-	+	-
63	<i>V. parahaemolyticus</i>	SAK11	clinical	-	+	-	-	+	-	-	+	-
64	<i>V. parahaemolyticus</i>	BAC-98-3547	clinical	-	+	-	-	+	-	-	+	-
65	<i>V. parahaemolyticus</i>	CT02006286	clinical	-	+	-	-	+	-	-	+	-

66	<i>V. parahaemolyticus</i>	HC-20-01	environmental	-	+	-	-	+	-	-	+	-
67	<i>V. parahaemolyticus</i>	CT02006628	clinical	-	+	-	-	+	-	-	+	-
68	<i>V. parahaemolyticus</i>	HC-05-01	environmental	-	+	-	-	+	-	-	+	-
69	<i>V. parahaemolyticus</i>	BAC-98-3483	clinical	-	+	-	-	+	-	-	+	-
70	<i>V. parahaemolyticus</i>	DAL 1094	unknown	-	+	-	-	+	-	-	+	-
71	<i>V. parahaemolyticus</i>	049-2A	oyster	-	+	-	-	+	-	-	+	-
72	<i>V. parahaemolyticus</i>	10329	clinical	-	+	-	-	+	-	-	+	-
73	<i>V. parahaemolyticus</i>	9401416	clinical	-	+	-	-	+	-	-	+	-
74	<i>V. parahaemolyticus</i>	48215	clinical	-	+	-	-	+	-	-	+	-
75	<i>V. parahaemolyticus</i>	954625	unknown	-	+	-	-	+	-	-	+	-
76	<i>V. parahaemolyticus</i>	9401392	clinical	-	+	-	-	+	-	-	+	-
77	<i>V. parahaemolyticus</i>	14D1	environmental	-	+	-	-	+	-	-	+	-
78	<i>V. parahaemolyticus</i>	VP43-1A	unknown	-	+	-	-	+	-	-	+	-
79	<i>V. parahaemolyticus</i>	659 110-1	environmental	-	+	-	-	+	-	-	+	-
80	<i>V. parahaemolyticus</i>	330 3B	environmental	-	+	-	-	+	-	-	+	-
81	<i>V. parahaemolyticus</i>	330 6	environmental	-	+	-	-	+	-	-	+	-
82	<i>V. parahaemolyticus</i>	1300 A2-1	environmental	-	+	-	-	+	-	-	+	-
83	<i>V. parahaemolyticus</i>	337 111	environmental	-	+	-	-	+	-	-	+	-
84	<i>V. parahaemolyticus</i>	872 247-1	environmental	-	+	-	-	+	-	-	+	-
85	<i>V. parahaemolyticus</i>	AO-24491	clinical	-	+	-	-	+	-	-	+	-
86	<i>V. parahaemolyticus</i>	AP-11243	clinical	-	+	-	-	+	-	-	+	-
87	<i>V. parahaemolyticus</i>	AN-2189	clinical	-	+	-	-	+	-	-	+	-
88	<i>V. parahaemolyticus</i>	DI-B9 3/16	environmental	-	+	-	-	+	-	-	+	-
89	<i>V. parahaemolyticus</i>	TX 2103	clinical	-	+	-	-	+	-	-	+	-
90	<i>V. parahaemolyticus</i>	SPRC 10295	clinical	-	+	-	-	+	-	-	+	-
91	<i>V. parahaemolyticus</i>	FIHES-98-V1	clinical	-	+	-	-	+	-	-	+	-
92	<i>V. parahaemolyticus</i>	AQ 4913	clinical	-	+	-	-	+	-	-	+	-
93	<i>V. parahaemolyticus</i>	DI-E12 5/26	environmental	-	+	-	-	+	-	-	+	-
94	<i>V. parahaemolyticus</i>	F11-3A	environmental	-	+	-	-	+	-	-	+	-
95	<i>V. parahaemolyticus</i>	48057	clinical	-	+	-	-	+	-	-	+	-
96	<i>V. parahaemolyticus</i>	R57	oyster	-	+	-	-	+	-	-	+	-
97	<i>V. parahaemolyticus</i>	R51	oyster	-	+	-	-	+	-	-	+	-
98	<i>V. parahaemolyticus</i>	R31	oyster	-	+	-	-	+	-	-	+	-
99	<i>V. parahaemolyticus</i>	R10	oyster	-	+	-	-	+	-	-	+	-
100	<i>V. parahaemolyticus</i>	R5	oyster	-	+	-	-	+	-	-	+	-

101	<i>V. vulnificus</i>	AM47548	clinical	-	-	+	-	-	+	-	-	+
102	<i>V. vulnificus</i>	1007(O)	unknown	-	-	+	-	-	+	-	-	+
103	<i>V. vulnificus</i>	94-8-109	unknown	-	-	+	-	-	+	-	-	+
104	<i>V. vulnificus</i>	BUF 7211	clinical	-	-	+	-	-	+	-	-	+
105	<i>V. vulnificus</i>	R844-G9	environmental	-	-	+	-	-	+	-	-	+
106	<i>V. vulnificus</i>	NSV 5736 (CDC 9349-95)	clinical	-	-	+	-	-	+	-	-	+
107	<i>V. vulnificus</i>	K4767	clinical	-	-	+	-	-	+	-	-	+
108	<i>V. vulnificus</i>	DAL 79040 (CDC 9070-96)	clinical	-	-	+	-	-	+	-	-	+
109	<i>V. vulnificus</i>	ATL 9824	clinical	-	-	+	-	-	+	-	-	+
110	<i>V. vulnificus</i>	ATL 9579	clinical	-	-	+	-	-	+	-	-	+
111	<i>V. vulnificus</i>	99-520 DP-B8	oyster	-	-	+	-	-	+	-	-	+
112	<i>V. vulnificus</i>	99-584 DP-B12	oyster	-	-	+	-	-	+	-	-	+
113	<i>V. vulnificus</i>	99-578 DP-B1	oyster	-	-	+	-	-	+	-	-	+
114	<i>V. vulnificus</i>	99-796 DP-E7	oyster	-	-	+	-	-	+	-	-	+
115	<i>V. vulnificus</i>	98-641 DP-G8	oyster	-	-	+	-	-	+	-	-	+
116	<i>V. vulnificus</i>	99-780 DP-E1	oyster	-	-	+	-	-	+	-	-	+
117	<i>V. vulnificus</i>	2095/00	environmental	-	-	+	-	-	+	-	-	+
118	<i>V. vulnificus</i>	98-640 DP-E9	oyster	-	-	+	-	-	+	-	-	+
119	<i>V. vulnificus</i>	99-645 DP-C4	oyster	-	-	+	-	-	+	-	-	+
120	<i>V. vulnificus</i>	ATCC 33816	clinical	-	-	+	-	-	+	-	-	+
121	<i>V. vulnificus</i>	1003(O)	unknown	-	-	+	-	-	+	-	-	+
122	<i>V. vulnificus</i>	LOS 7506	clinical	-	-	+	-	-	+	-	-	+
123	<i>V. vulnificus</i>	ATL 64138(12)	clinical	-	-	+	-	-	+	-	-	+
124	<i>V. vulnificus</i>	NSV 5829 (CDC 9149-95)	clinical	-	-	+	-	-	+	-	-	+
125	<i>V. vulnificus</i>	DAL 8-9131(7)	clinical	-	-	+	-	-	+	-	-	+
126	<i>V. vulnificus</i>	ORL 8073	clinical	-	-	+	-	-	+	-	-	+
127	<i>V. vulnificus</i>	R499-A8	oyster	-	-	+	-	-	+	-	-	+
128	<i>V. vulnificus</i>	99-779 DP-D2	oyster	-	-	+	-	-	+	-	-	+
129	<i>V. vulnificus</i>	99-624 DP-C10	oyster	-	-	+	-	-	+	-	-	+
130	<i>V. vulnificus</i>	94-9-146	unknown	-	-	+	-	-	+	-	-	+
131	<i>V. vulnificus</i>	94-8-111	unknown	-	-	+	-	-	+	-	-	+
132	<i>V. vulnificus</i>	ATL 71491 (CDC 9074-96)	clinical	-	-	+	-	-	+	-	-	+

133	<i>V. vulnificus</i>	LOS 7343 (CDC 9062-96)	clinical	-	-	+	-	-	+	-	-	+
134	<i>V. vulnificus</i>	FLA 9509 (CDC 9003-97)	clinical	-	-	+	-	-	+	-	-	+
135	<i>V. vulnificus</i>	ORL 8324 (CDC 9340-95)	clinical	-	-	+	-	-	+	-	-	+
136	<i>V. vulnificus</i>	ATL 9823 (CDC 9352-94)	clinical	-	-	+	-	-	+	-	-	+
137	<i>V. vulnificus</i>	ATL 7-1503 (CDC 9075-96)	clinical	-	-	+	-	-	+	-	-	+
138	<i>V. vulnificus</i>	DAL 6-5000 (CDC 9345-95)	clinical	-	-	+	-	-	+	-	-	+
139	<i>V. vulnificus</i>	ORL 8074 (CDC 9032-95)	clinical	-	-	+	-	-	+	-	-	+
140	<i>V. vulnificus</i>	ATL 6-1306 (CDC 9031-96)	clinical	-	-	+	-	-	+	-	-	+
141	<i>V. vulnificus</i>	LOS 6966 (CDC 9342-95)	clinical	-	-	+	-	-	+	-	-	+
142	<i>V. vulnificus</i>	FLA 8869 (CDC 9053-96)	clinical	-	-	+	-	-	+	-	-	+
143	<i>V. vulnificus</i>	ATL 71504 (CDC 9076-96)	clinical	-	-	+	-	-	+	-	-	+
144	<i>V. vulnificus</i>	99-622 DP-E4	oyster	-	-	+	-	-	+	-	-	+
145	<i>V. vulnificus</i>	99-609 DP-A4	oyster	-	-	+	-	-	+	-	-	+
146	<i>V. vulnificus</i>	99-623 DP-F5	oyster	-	-	+	-	-	+	-	-	+
147	<i>V. vulnificus</i>	99-742 DP-A9	oyster	-	-	+	-	-	+	-	-	+
148	<i>V. vulnificus</i>	99-537 DP-G7	oyster	-	-	+	-	-	+	-	-	+
149	<i>V. vulnificus</i>	98-783 DP-A1	oyster	-	-	+	-	-	+	-	-	+
150	<i>V. vulnificus</i>	99-743 DP-B6	oyster	-	-	+	-	-	+	-	-	+

^aUS FDA MESC/Dauphin Island Sea Laboratory, Dauphin Island, AL

^bCenter for Disease Control and Prevention, Atlanta, GA

^cATCC = American Type Culture Collection, Manassas, VA

^dVc = *Vibrio cholera*

^eVp = *Vibrio parahaemolyticus*

^fVv = *Vibrio vulnificus*

88	<i>Salmonella arizonae</i>	CECT 4395	Unknown	-	-	-	-	-	-	-	-	-
89	<i>Salmonella Berta</i>	CMF 141.2	Unknown	-	-	-	-	-	-	-	-	-
90	<i>Salmonella bongori</i>	CIP 82.33T	Unknown	-	-	-	-	-	-	-	-	-
91	<i>Salmonella diarizonae</i>	CIP 82.31T	Unknown	-	-	-	-	-	-	-	-	-
92	<i>Salmonella Dublin</i>	CIP 106222	Unknown	-	-	-	-	-	-	-	-	-
93	<i>Aeromonas hydrophila/caviae</i>	ATCC 13136	Unknown	-	-	-	-	-	-	-	-	-
94	<i>Salmonella houtenae</i>	CIP82.32T	Unknown	-	-	-	-	-	-	-	-	-
95	<i>Salmonella salamae</i>	CECT 4000	Unknown	-	-	-	-	-	-	-	-	-
96	<i>Serratia liquefacians</i>	25792 ^c	Unknown	-	-	-	-	-	-	-	-	-
97	<i>Serratia marcescens</i>	ATCC 8100	Unknown	-	-	-	-	-	-	-	-	-
98	<i>Shewanella putrefaciens</i>	FT-507 ^c	Unknown	-	-	-	-	-	-	-	-	-
99	<i>Shigella boydii</i>	ATCC 9207	Pork Liver	-	-	-	-	-	-	-	-	-
100	<i>Shigella flexneri</i>	ATCC 12022	Unknown	-	-	-	-	-	-	-	-	-
101	<i>Shigella sonnei</i>	ATCC 25931	Unknown	-	-	-	-	-	-	-	-	-
102	<i>Siccibacter turicensis</i>	CCUG 54945 ⁱ	Unknown	-	-	-	-	-	-	-	-	-
103	<i>Staphylococcus aureus</i>	ATCC 25923	Unknown	-	-	-	-	-	-	-	-	-
104	<i>Staphylococcus epidermidis</i>	ATCC 14990	Nose	-	-	-	-	-	-	-	-	-
105	<i>Staphylococcus haemolyticus</i>	ATCC 29970	Human Skin	-	-	-	-	-	-	-	-	-
106	<i>Staphylococcus hominis</i>	ATCC 27844	Human Skin	-	-	-	-	-	-	-	-	-
107	<i>Staphylococcus intermedius</i>	61.221 ^c	Unknown	-	-	-	-	-	-	-	-	-
108	<i>Staphylococcus sciuri</i>	QL 17041.9	Raw Milk	-	-	-	-	-	-	-	-	-
109	<i>Staphylococcus warneri</i>	ATCC 29885	Unknown	-	-	-	-	-	-	-	-	-
110	<i>Enterobacter asburiae</i>	ATCC 35956	Human	-	-	-	-	-	-	-	-	-
111	<i>Streptococcus agalactiae</i>	ATCC BAA-22	Unknown	-	-	-	-	-	-	-	-	-
112	<i>Streptococcus pneumoniae</i>	ATCC 6301	Unknown	-	-	-	-	-	-	-	-	-
113	<i>Streptococcus pyogenes</i>	ATCCC 19615	Child's Pharynx	-	-	-	-	-	-	-	-	-
114	<i>Walleimia sebi</i>	CECT 20820	Unknown	-	-	-	-	-	-	-	-	-
115	<i>Yersinia enterocolitica</i>	CIP 80.27T	Unknown	-	-	-	-	-	-	-	-	-
116	<i>Zygosaccharomyces rouxii</i>	DSM 7525	Unknown	-	-	-	-	-	-	NG	NG	NG

^aCIP=Collection Institute Pasteur, Paris, France

^bATCC = American Type Culture Collection, Manassas, VA

^cUS FDA MESC/Dauphin Island Sea Laboratory, Dauphin Island, AL

^dLMG=Belgian Coordinated Collections of Microorganisms, Ghent, Belgium

^eQL = Q Laboratories, Cincinnati, OH

^fDSM=The Leibniz Institute DSMZ, Brunswick, Germany

^gCECT=Spanish Type Culture Collection. Valencia, Spain

^hFSL= Cornell University, Ithaca, NY

ⁱCNR= Centre National de référence des Legionelles, Lyon, France

^jCCUG= Culture Collection University of Gothenburg, DSMZ, Braunschweig, Germany

^kVc = *Vibrio cholera*

^lVp = *Vibrio parahaemolyticus*

^mVv = *Vibrio vulnificus*

ⁿNG = No Growth

Table 9: Candidate vs. FDA/BAM Chapter 9 Qualitative Reference Method– POD Results (1)

Matrix	Strain	Enrichment & Time Point ^a	MPN ^b Test Portion	N ^c	Candidate ⁱ			Reference			dPOD _c ^g	95% CI ^h
					X ^d	POD _c ^e	95% CI	X	POD _R ^f	95% CI		
Cooked Shrimp (125 g)	<i>V. cholerae</i> QL 433.1	VEB ^j 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.51 (0.27, 0.86)	20	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.23, 0.32
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Cooked Shrimp (125 g)	<i>V. cholerae</i> QL 433.1	APW ^k 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.51 (0.27, 0.86)	20	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.23, 0.32
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Cooked Shrimp (25 g) ^a	<i>V. cholerae</i> QL 433.1	APW 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.27, 0.86)	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Mussels (25 g)	<i>V. cholerae</i> QL 433.1	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.51 (0.26, 0.86)	20	8	0.40	0.22, 0.61	6	0.30	0.15, 0.52	0.10	-0.18, 0.36
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Mussels (25 g) ^a	<i>V. cholerae</i> QL 433.1	APW 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.26, 0.86)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.13, 0.13
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

^aIdentical results produced between 6 h and 18 h enrichment time points for test portions enriched with APW.

^bMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval

^cN = Number of test portions

^dx = Number of positive test portions

^ePOD_c = Candidate method confirmed positive outcomes divided by the total number of trials

^fPOD_R = Reference method confirmed positive outcomes divided by the total number of trials

^gdPOD_c = Difference between the confirmed candidate method result and reference method confirmed result POD values

^h95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

ⁱTest portions analyzed on the iQ-Check Prep with and without Free DNA Removal Step, and identical results were produced.

^jVEB = *Vibrio* Enrichment Broth

^kAPW = Alkaline Peptone Water

Table 10: Candidate vs. FDA/BAM Chapter 9 Quantitative/MPN Reference Method– POD Results (1)

Matrix	Strain	Enrichment & Time Point	MPN ^c Test Portion	N ^d	Candidate ^j			Reference ^b			dPOD _c ^h	95% CI ⁱ
					X ^e	POD _c ^f	95% CI	X	POD _R ^g	95% CI		
Raw Shrimp (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	VEB ^k 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.39 (0.18, 0.68)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.27, 0.27
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Shrimp (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	APW ^l 6 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.39 (0.18, 0.68)	20	3	0.15	0.05, 0.36	6	0.30	0.15, 0.52	-0.15	-0.39, 0.11
			1.97 (0.91, 4.27)	5	2	0.40	0.12, 0.77	5	1.00	0.57, 1.00	-0.60	-0.88, -0.03
		APW 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.39 (0.18, 0.68)	20	5	0.25	0.11, 0.47	6	0.30	0.15, 0.52	-0.05	-0.31, 0.22
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Oysters (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.45 (0.22, 0.78)	20	7	0.35	0.18, 0.57	8	0.40	0.22, 0.61	-0.05	-0.32, 0.23
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Oysters (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	APW ^a 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.45 (0.22, 0.78)	20	7	0.35	0.18, 0.57	8	0.40	0.22, 0.61	-0.05	-0.32, 0.23
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Tuna (25 g)	<i>V. vulnificus</i> QL 021111A	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.50 (0.25, 0.86)	20	6	0.30	0.15, 0.52	7	0.35	0.18, 0.57	-0.05	-0.32, 0.23
			3.70 (1.52, 9.02)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw Tuna (25 g)	<i>V. vulnificus</i> QL 021111A	APW ^a 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
			0.50 (0.25, 0.86)	20	8	0.40	0.22, 0.61	7	0.35	0.18, 0.57	0.05	-0.23, 0.32
			3.70 (1.52, 9.02)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

^aIdentical results produced between 6 h and 18 h enrichment time points for test portions enriched with APW.

^bReference test portions derived from the 30 sets of dilution series used for the FDA/BAM Chapter 9 Quantitative/MPN reference method.

^cMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval

^dN = Number of test portions

^ex = Number of positive test portions

^fPOD_c = Candidate method confirmed positive outcomes divided by the total number of trials

^gPOD_R = Reference method confirmed positive outcomes divided by the total number of trials

^hdPOD_c = Difference between the confirmed candidate method result and reference method confirmed result POD values

ⁱ95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

^jTest portions analyzed on the iQ-Check Prep with and without Free DNA Removal Step, and identical results were produced.

^kVEB = *Vibrio* Enrichment Broth

^lAPW = Alkaline Peptone Water

Table 11: Presumptive vs. Confirmed – POD Results- Qualitative Method (1)

Matrix	Strain	Enrichment & Time Point ^a	MPN ^c / Test Portion	N ^d	Presumptive			Confirmed ^b			dPOD _{CP} ^h	95% CI ⁱ
					X ^e	POD _{CP} ^f	95% CI	X	POD _{CC} ^g	95% CI		
Cooked Shrimp (125g)	<i>V. cholerae</i> QL 433.1	VEB ^j 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.27, 0.86)	20	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cooked Shrimp (125 g)	<i>V. cholerae</i> QL 433.1	APW ^k 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.27, 0.86)	20	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Cooked Shrimp (25 g)	<i>V. cholerae</i> QL 433.1	APW 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.27, 0.86)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Mussels (25 g)	<i>V. cholera</i> QL 433.1	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.26, 0.86)	20	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Mussels (25 g)	<i>V. cholerae</i> QL 433.1	APW 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.51 (0.26, 0.86)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.13, 0.13
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

^aIdentical results produced between 6 h and 18 h enrichment time points for test portions enriched with APW.

^bIdentical results produced between the FDA/BAM Chapter 9 Reference confirmation and alternative confirmation method.

^cMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval

^dN = Number of test portions

^ex = Number of positive test portions

^fPOD_{CP} = Candidate method presumptive positive outcomes divided by the total number of trials

^gPOD_{CC} = Candidate method confirmed positive outcomes divided by the total number of trials

^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed result POD values

ⁱ95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

^jVEB = *Vibrio* Enrichment Broth

^kAPW - Alkaline Peptone Water

Table 12: Presumptive vs. Confirmed – POD Results- Quantitative Method (1)

Matrix	Strain	Enrichment & Time Point	MPN ^c / Test Portion	N ^d	Presumptive			Confirmed ^b			dPOD _{CP} ^h	95% CI ⁱ
					X ^e	POD _{CP} ^f	95% CI	X	POD _{CC} ^g	95% CI		
Raw Shrimp (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	VEB ^j 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.39 (0.18, 0.68)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Shrimp (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	APW ^k 6 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.39 (0.18, 0.68)	20	3	0.15	0.05, 0.36	3	0.15	0.05, 0.36	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	2	0.40	0.12, 0.77	2	0.40	0.12, 0.77	0.00	-0.47, 0.47
		APW 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.39 (0.18, 0.68)	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.13, 0.13
			1.97 (0.91, 4.27)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Oysters (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.45 (0.22, 0.78)	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Oysters (25 g)	<i>V. parahaemolyticus</i> ATCC 17802	APW ^a 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.45 (0.22, 0.78)	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
			2.58 (1.15, 5.78)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Tuna (25 g)	<i>V. vulnificus</i> QL 021111A	VEB 7 h (Unpaired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.50 (0.25, 0.86)	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	-0.13, 0.13
			3.70 (1.52, 9.02)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Raw Tuna (25 g)	<i>V. vulnificus</i> QL 021111A	APW ^a 6 h & 18 h (Paired)	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
			0.50 (0.25, 0.86)	20	8	0.40	0.22, 0.61	8	0.40	0.22, 0.61	0.00	-0.13, 0.13
			3.70 (1.52, 9.02)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

^aIdentical results produced between 6 h and 18 h enrichment time points for test portions enriched with APW.

^bIdentical results produced between the FDA/BAM Chapter 9 Reference confirmation and alternative confirmation method.

^cMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 1.6 provided by AOAC RI, with 95% confidence interval

^dN = Number of test portions

^ex = Number of positive test portions

^fPOD_{CP} = Candidate method presumptive positive outcomes divided by the total number of trials

^gPOD_{CC} = Candidate method confirmed positive outcomes divided by the total number of trials

^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed result POD values

ⁱ95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

^jVEB = *Vibrio* Enrichment Broth

^kAPW - Alkaline Peptone Water

DISCUSSION OF THE MODIFICATION STUDY APPROVED JANUARY 2023 (3)

The new CFX Opus Deepwell instrument delivers the same performance as the current CFX96 Touch Deep Well instrument but with a more modern design and cloud capabilities. The improved stability of the thermal block ensures a more uniform thermal protocol. The CFX Manager Software, IDE v 3.1 brings the same performance, algorithm, and interpretation as the current CFX Manager Software, IDE v 3.0 with the only change being compatibility to both CFX96 Touch Deep Well and CFX Opus Deepwell instruments.

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2. FDA/BAM Chapter 9: *Vibrio*. May 2004. (Accessed December 2019) <https://www.fda.gov/food/laboratory-methods-food/bam-vibrio>
3. Clark, M., Validation of the Group Modification for the Addition of the CFX Opus Deepwell Real-Time PCR Instrument and CFX Manager Software, IDE v3.1, AOAC *Performance Tested Methods*SM certification number 031209. Modification approved January 2023.